K100710

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

510(K) SUMMARY

APR 2 8 2010

1. Administrative Information

Name:	St. Jude Medical
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Contact Person:	Jennifer Zwiefelhofer Senior Regulatory Affairs Specialist
Date:	February 19, 2009

2. Device Information

Name of Device:	Roll-X™ Interventional Guidewire Portfolio
Common Name:	Guidewire
Classification Name:	Catheter Guidewire (870.1330)
Product Code:	DQX

3. Predicate Device Information

Roll-X™ Guidewire (St. Jude Medical) - K082304 cleared Aug 2008
Asahi Prowater PTCA Coronary Guidewire (Abbott) - K052339 cleared Nov 2005
Hi-Torque Balance Middleweight Universal (Abbott) - K013833 cleared Jan 2002
Hi-Torque Balance Heavyweight Guidewire (Abbott) - K982083 cleared Sep 1998

4. Device Description

Roll-X™ Guidewires are steerable guidewires constructed of a stainless steel core wire with a coiled wire spring design at the distal end. The core wire is PTFE coated. Roll-X™ Guidewires have a unique distal end design to enhance torque response and control. The distal end of the guidewire is shapeable and is radiopaque. The guidewires are provided sterile and non-pyrogenic.

5. Intended Use

Roll-X Guidewires are intended to facilitate the placement of balloon dilation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The wires are also intended to facilitate the placement of compatible interventional devices during therapeutic intravascular procedures. The guidewires are not to be used in cerebral blood vessels.

6. Technological Characteristics

The Roll-X Guidewires as compared to the Roll-X, Asahi Prowater, Hi-Torque BMW and Hi-Torque BHW guidewires are substantially equivalent in many ways, including intended use, design, material types, and technology as outlined below.

Intended Use:

- Roll-X, Prowater, BMW and BHW guidewires have the same intended indication which is to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The wire is also intended to facilitate the placement of compatible interventional devices during therapeutic intravascular procedures.

Product Design, Material Types and Technology:

- Sized 0.014"
- Available in similar lengths (180, 185 or 190cm and 300 cm)
- Contain a SST core wire
- Contain a distal radiopaque coil
- Have flexible tip designs that can be shaped by the user
- Are joined by a combination of solders, welds, and/or adhesives
- Proximal SST cores wires are PTFE coated
- Contain a hydrophilic coating on the distal end

7. Summary of Non-clinical Testing

Performance testing of the Roll-X Guidewires consists of bench and animal testing. Results of the testing demonstrate that the guidewire design meets product specifications and intended uses. A summary of the bench and performance testing conducted is listed below:

Performance Testing Summary

Item	Tests
Device performance	• Tensile Strength • Torque Strength • Torqueability • Tip Flexibility • Catheter Compatibility • Coating Adherence/Integrity •Flexing Test •Fracture Test •Corrosion Resistance •Radiopacity •Steering Response •Tip Load Test
Biocompatibility	• Cytotoxicity • Sensitization • Irritation • Acute Systemic Toxicity • Hemolysis • Partial Thromboplastin Time • Complement Activation • In vivo Thromboresistance
Sterilization/Microbiology	• Ethylene Oxide Sterilization Evaluation • Bioburden • EO residuals • Endotoxin
Packaging	• Pouch Peel Test • Visual Inspection • Pouch Seal Integrity
Shelf Life	• Same as device performance and packaging
Animal Testing	• Study #1 – assess performance as compared to currently marketed guidewire • Study #2 – development of hydrophilic coating scheme

8. Substantial Equivalence Conclusion

The Roll-X™ Guidewires described in this 510(k) are substantially equivalent to the St. Jude Medical Roll-X™ Guidewire (K082304), the Abbott Vascular ASAHI Prowater Coronary Guidewire (K052339), the Abbot Vascular (previously Guidant Vascular Intervention) Hi-Torque Balance Middleweight™ Universal Guidewire (K013833) and the Abbot Vascular (previously Guidant Vascular Intervention) Hi-Torque® Balance Heavy Weight Guidewire (K982083). The intended use, design, material types, technology, and performance of the Roll-X™ Guidewires are equivalent to the predicate devices. There are no differences between devices which would raise issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

St. Jude Medical
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technologies Services LLC
1394 25th Street NW
Buffalo, MN 55313

APR 2 8 2010

Re: K100710
Trade/Device Name: Roll-X™ Interventional Guidewire Portfolio
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guidewire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: March 11, 2010
Received: March 12, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100710

Device Name: Roll-X™ Interventional Guidewire Portfolio

Indications For Use:

Roll-X Guidewires are intended to facilitate the placement of balloon dilation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The wires are also intended to facilitate the placement of compatible interventional devices during therapeutic intravascular procedures. The guidewires are not to be used in cerebral blood vessels.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vuchinich
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100710